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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH CENTRAL DIVISION

BRIGHAM YOUNG UNIVERSITY, a Utah Non-Profit Education Institution; and Dr. DANIEL L. SIMMONS, an individual, Plaintiffs, vs. PFIZER, INC., a Delaware corporation; G.D. SEARLE & COMPANY, a Delaware corporation; G.D. SEARLE LLC, a Delaware limited liability company; MONSANTO COMPANY, a Delaware corporation; and PHARMACIA CORPORATION, a Delaware corporation, Defendants.	Case Number: 2:06-CV-890-TS (BCW) **MEMORANDUM IN SUPPORT OF MOTION FOR PERMISSION TO PROVIDE DESIGNATED DOCUMENTS TO TEVA PHARMACEUTICALS THAT PFIZER HAS LABELED AS CONFIDENTIAL UNDER THE PROTECTIVE ORDER** Judge Ted Stewart Magistrate Judge Brooke C. Wells

INTRODUCTION AND BACKGROUND

Plaintiffs Brigham Young University and Daniel L. Simmons (collectively, "BYU") seek the Court's permission pursuant to paragraph 20 of the Protective Order entered in this case to provide to Teva Pharmaceuticals USA, Inc. ("Teva") copies of 22 motions, including responses, accompanying exhibits, and orders resolving the same, along with the expert reports exchanged in this case (the "Designated Documents").[1] For its part, Teva will sign a form of the "Declaration and Agreement to be Bound" appended to the Protective Order, and thus agree to be bound by the terms of the Protective Order, except that Teva would not use the documents for this litigation, but only for evaluating a possible transaction with BYU.

Teva wants to review the Designated Documents as part of its due diligence in deciding whether to enter into an option agreement with BYU, pending the outcome of the inventorship claims in this litigation.[2] Teva is a generic drug manufacturer. On its own initiative, and without encouragement from BYU, Teva learned about this litigation and reviewed certain publicly-available documents from this litigation.[3] Teva thus became aware that BYU asserts, among other things, that Pfizer failed to name Plaintiff Dr. Daniel Simmons as a co-inventor of various COX-2 related patents (the "Co-Inventorship Rights").[4] Teva contacted BYU and expressed an interest in obtaining a license from BYU to utilize the Co-Inventorship Rights, in the event such

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[1] *See* Exs. A and C to Agreement between Teva and BYU, 23 Jan 12, attached here to as Ex. 1. Exhibit A is a list of various motions, responses, orders and exhibits that BYU wants to provide to Teva and Exhibit B is a list of the expert reports that BYU wants to provide to Teva. Together, Exhibits A and B comprise the "Designated Documents."

[2] On January 23, 2012, BYU and Teva executed an Agreement (the "Agreement"), a copy of which is attached as Exhibit 1. That Agreement establishes a basis and certain requirements for the parties to negotiate an option agreement for the licensing of the Co-Inventorship rights sought by BYU in this litigation.

[3] Agreement, 23 Jan 12, Ex. 1 at 1.

[4] *Id.*

rights are obtained in this lawsuit.[5] Teva has also expressed a willingness to make a substantial upfront payment to BYU that is not dependent upon the outcome of the litigation. For these reasons, Teva wants to conduct appropriate due diligence on the claims, and BYU, in the interest of full disclosure, desires to enable Teva to do so.

Because Pfizer has in this case labeled the Designated Documents as "Confidential" or "Highly Confidential," the Protective Order bars BYU from sharing them with Teva, absent the Court's permission.

In considering the matter, it is important to understand that Pfizer itself has already provided Teva with many of these documents. Teva was previously involved in COX-2 litigation with Pfizer.[6] According to Pfizer, in that prior litigation Pfizer produced to Teva most, if not all, of the same COX-2-related documents Pfizer produced to BYU in this case. (After that litigation was resolved, Teva subsequently destroyed the documents pursuant to the protective order in place in that litigation.)

Also according to Pfizer, when Pfizer predecessors Monsanto, Searle and Pharmacia were involved in litigation with the University of Rochester, they made a thorough search for, and production of, all their COX-2-related documents. They then represented to having produced those documents, and more, to Teva, in the subsequent litigation with Teva. Since Teva thus has already had prior access to much of the information contained in the documents BYU proposes to provide Teva now, BYU believes that providing such documents to Teva a second time will not prejudice Pfizer in any material way. Moreover, because Teva was enjoined in the prior litigation from selling Celebrex until the patent expires, Teva could not now use such information to compete with Pfizer. In any event, the documents are for the most part 20 years

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[5] *Id.*

[6] *Id.*

old, and their current sensitivity, either to a potential competitor such as Teva or otherwise, is doubtful at best..

On 25 January 2012, BYU and Pfizer had a telephonic "meet and confer" in which BYU presented its request in an attempt to resolve these issues without involving the Court, but were unable to reach an agreement. As part of those discussions, BYU offered that—if Pfizer could point to particular documents or portions thereof included in the group BYU wanted to share with Teva that Pfizer believed were truly prejudicial—BYU would consider excluding those documents or portions. On 30 January, the parties again conferred on the matter and Pfizer advised that it would not agree to allow any of the documents to be seen by Teva.

Hence, BYU brings the current motion.

I. PFIZER PREVIOUSLY PRODUCED COX-2 RELATED DOCUMENTS TO TEVA AFTER IT SUED TEVA IN 2004.

A. Dr. Simmons's Discovery Of COX-2 Leads To Celebrex.

In 1989, Plaintiff Dr. Dan Simmons of BYU became the first person to clone a second cyclooxygenase, "COX-2," and Dr. Simmons recognized it had the potential to be the basis for a new drug that, by specifically inhibiting COX-2 but not COX-1, could reduce inflammation without some of the side effects of traditional non-steroidal anti-inflammatory drugs, or "NSAIDs," such as aspirin and Advil.[7] After spending some years doing further research on the matter, Dr. Simmons, on 29 April 1991, provided Pfizer-predecessor Monsanto with his proprietary mCOX-1 and mCOX-2 clones along with other proprietary information, preliminary to finalizing a two-year Research Agreement (the "Agreement") with Monsanto for the purpose of collaborating on the development of a COX-2 selective NSAID.[8]

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[7] Pls. Resp. in Opp. to Mot. for Part. Sum. J. (Stat. of Limitations), Dkt. 510, 18 Dec 10, at pp. 8-9, ¶¶ 8-13.

[8] *Id.* at pp. 10-11, 14, 16-17, ¶¶ 14-16; 26; 33-34.

BYU asserts that, after secretly using Dr. Simmons's proprietary materials in their private work, Monsanto scientists in March 1992 discovered a potentially-patentable COX-2 inhibitor, and took steps to terminate the Agreement with BYU.[9] In November 1993, Monsanto then filed a patent application with the U.S. Patent and Trademark Office (the "PTO") for celecoxib, the working ingredient in what became known as Celebrex.[10] Based on that application, the PTO in 1995 issued Monsanto U.S. Patent No. 5,466,823 (the "'823 patent"). Monsanto applied for and was issued various other COX-2 patents related to the '823 patent.

In February 1999, Monsanto and its parent, G.D. Searle, with co-promotion by Pfizer, began selling Celebrex.[11]

B. Monsanto Has Been Embroiled In COX-2 Litigation And Gathering Relevant Documents Since Before It Received The Celebrex Patent, And For At Least A Dozen Years Before This Suit.

Even before receiving the Celebrex '823 patent, Monsanto was involved in litigation relating to its COX-2 program. Indeed, according to a sworn affidavit of Pfizer witness Patricia O'Brien, "[l]itigation involving the COX-2 research program has been going on since at least 1994."[12] That early litigation included litigation with Merck over Merck's competing COX-2 selective drug, Vioxx, which Monsanto specifically anticipated by 1995.[13]

By no later than December 1999, Monsanto specifically anticipated litigation with BYU over Celebrex, and began gathering documents relating to that anticipated litigation.[14]

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[9] *Id.* at pp. 37-39, ¶¶ 101-108.

[10] *Id.* at p. 35, ¶ 95.

[11] Dkt. 442, First Amended Complaint, ¶ 170.

[12] Affidavit of P. O'Brien, 30 Sep 05, paragraph 8 (marked as Dep. Ex. 239 in this case); copy attached as Exhibit 2.

[13] Amd. Memo. For Further Discovery Sanctions, Dkt. 768, 9 Dec 11, at p. 28, ¶ 93.

[14] *Id.* at pp. 27-28, ¶ 92.

As Pfizer stated in a memorandum filed in this case:

> Pfizer has been involved in several prior litigations relating to COX-2 and COX-2 inhibitors, including most prominently the *Rochester* and *Teva* litigations.[15]

C. Pfizer Claims To Have Produced Virtually All COX-2 Documents To Both Rochester and Teva.

1. The *Rochester* litigation.

In April 2000, the University of Rochester ("Rochester") sued Monsanto, Searle, and Pfizer in the Western District of New York, asserting that Pfizer's sales of Celebrex infringed a Rochester COX-2-related patent (the "*Rochester*" litigation). According to Pfizer:

> During the *Rochester* litigation, Pfizer performed a good faith search of its files for virtually all technical documents related to COX-2 and produced hard copies of those documents during that litigation.[16]

As Pfizer has also asserted, the "breadth of Pfizer's document production in the *Rochester* litigation" was "evident" from the document requests Rochester served in that case. For example, said Pfizer, Rochester's Request 1 sought:

> All documents concerning, recounting, referring to, summarizing, analyzing or relating to the identification and/or development of Celebrex as a cox-2 inhibitor.[17]

In addition, Pfizer pointed out that Rochester's document request 71 specifically sought documents related to BYU:

> All communications…between (1) Defendants and (2) Daniel Simmons, any representative of Brigham Young University, or those working with them that summarize, describe or refer to Defendants' actual or contemplated use of animals, cells, other

[15] Dfs. Mem. in Opp. to Mot. to Compel Immed. Prod. of Docs., 25 Jan 08, Dkt. 69, at p. 2.

[16] *Id.*, Dkt. 69, 25 Jan 08, at p. 2.

[17] *Id.*

> biological materials, or genetic materials that were received, examined or used in connection with Defendants' research on cyclooxygenase, cyclooxygenase-2, cox-2 inhibitors or a dexamethasone induced protein.[18]

2. The *Teva* Litigation.

Teva is a generic drug manufacturer. As permitted by U.S. patent law, Teva filed with the United Stated Food and Drug Administration (the "FDA") an Abbreviated New Drug Application ("ANDA"), seeking approval to sell celecoxib as a generic drug. Such an ANDA may be filed even for drugs protected by patents, if the applicant certifies, as Teva did, that the relevant patents were invalid. However, the applicant must notify the patent holder of the ANDA.

After learning of Teva's ANDA, Pfizer sued Teva in February 2004 in the United States District Court, District of New Jersey, alleging that the ANDA infringed Pfizer's '823 celecoxib patent, as well as two other COX-2-related patents (the "*Teva* Litigation"). For its part, Teva argued, among other things, that the '823 patent was invalid.

In this litigation, Pfizer has claimed that during the *Teva* litigation Pfizer "produced documents from the *Rochester* litigation that were dated prior to 1995, as well as some additional documents collected during the *Teva* Litigation.[19] Pfizer eventually prevailed in the *Teva* litigation, and in April 2007, the court issued a final judgment enjoining Teva from selling Celebrex until the patent expired.[20]

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[18] *Id.* at p.3.

[19] *Id.* Pfizer said it later discovered that "the *Teva* production primarily contain[ed] documents dated after January 1992." *Id.* at p. 4.

[20] The Federal Circuit later modified that order in part. *See Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008).

D. According To Pfizer, Most Of The Documents BYU Sought In This Litigation Were Produced In *Teva*.

In response to BYU's first request for production, Pfizer in July 2007 stated that it had "produced the complete *Teva* production to BYU," a production that it said "allowed BYU to access over two million pages of documents."[21] Per Pfizer, it "reasonably believes the *Teva* production adequately responds to the vast majority of plaintiffs' document requests…"[22]

II. PROVIDING THE DESIGNATED DOCUMENTS TO TEVA WILL NOT PREJUDICE PFIZER.

The Protective Order specifically allows the Court to permit disclosure of information "more broadly than would otherwise be permitted by the terms of th[e] Protective order."[23] Such additional disclosure to Teva of the discrete set of Designated Documents at issue here is appropriate for at least four reasons:

First, as Pfizer itself has represented in this lawsuit, Pfizer has previously produced most of the documents at issue to Teva.

Second, if the Court permits disclosure of the Designated Documents to Teva, Teva will sign a version of the Declaration and Agreement to Be Bound by the Protective Order, except that it may use confidential information obtained from the Designated Documents for the purpose of evaluating the contemplated option agreement.

Third, a primary purpose of the Protective Order is to prevent the disclosure of information "which is likely to cause harm to the competitive position of the producing

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[21] Dfs. Mem. in Opp. to Mot. to Compel Immed. Prod. of Docs., Dkt. 69, 25 Jan 08 at p. 3.

[22] Ltr. to L. R. Williams from L. Schneider, 22 Oct 07, at 4, attached as Exhibit 3.

[23] Protective Order, Dkt. 43, 7 Jun 07, at p. 14, ¶ 18(f); *see also id.* at p. 15, ¶ 20 ("Nothing in this Protective order shall prevent disclosure beyond the terms of this Order … if the Court, after notice to all affected parties, orders such disclosure"); at p. 18, ¶ 25 ("Nothing in this Protective Order shall prejudice the right of any party, or any third party, to seek relief from the Court, upon good cause shown, from any of the restrictions provided above …").

party…"[24] Here, because an injunction has already been entered against Teva barring it from selling Celebrex until the patent expires, Teva could not, as a matter of law, use any of the information to a competitive advantage vis-à-vis Pfizer. Furthermore, the information to be provided is generally 20 years old.

In addition, the Protective Order itself shows that Pfizer was not concerned about disclosures to Teva employees, provided they agreed to the terms of the Protective Order. Paragraph 4(c) of the Protective Order expressly allows the parties to share confidential information with retained scientific and technical consultants and experts. Logically, and as both parties understood, many such consultants and experts would be those who were currently, or had in the past been, involved in the pharmaceutical industry. But—with only two exceptions—the Protective Order does not restrict the pharmaceutical companies that could receive such disclosures.

The two exceptions set out at paragraph 4(c) are Merck & Co. and Boehringer Ingelheim: the Order specifically bars BYU from providing any protected information to "any past or present officers, employees, representatives or agents" of those two companies. But paragraph 4(c) does not bar disclosures to Teva. As a result, BYU could have, without the Court's permission and without Pfizer's knowledge, engaged Teva employees as expert consultants in this case and shared confidential information with them.

And ironically, despite the specific prohibition against disclosures to any past or present employee of Merck, Dr. Joseph Mancini—one of Pfizer own experts to whom it has given access to otherwise confidential documents in this lawsuit—is a former employee of Merck. Pfizer is plainly not seriously concerned about the disclosure of such information to other pharmaceutical companies.

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[24] *Id.* at p. 3, ¶ 2.

Finally, any minimal concerns about Pfizer's interests in preserving the confidentiality of these documents should not stand in the way of the potential substantial benefits that could flow to BYU from the transaction with Teva. And if Pfizer believes that any particular document or documents pose a real risk to Pfizer, Pfizer can raise that issue with the Court.

CONCLUSION

The disclosure of the Designated Documents to Teva, in confidence, will not prejudice Pfizer in any material way. The Court should therefore allow the disclosure.

RESPECTFULLY SUBMITTED this 31st day of January, 2012.

BEUS GILBERT PLLC

By *__/s/ Mark C. Dangerfield__*
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CERTIFICATE OF SERVICE

I hereby certify that on the 31st day of January, 2012, I electronically filed the foregoing Memorandum In Support Of Permission To Provide Designated Documents To Teva Pharmaceuticals That Pfizer Has Labeled As Confidential Under The Protective Order, with the Clerk of the United States District, District of Utah Central Division, using the CM/ECF system which sent notification of such filing to the following:

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